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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,578	11/28/2005	Narinder K. Chawla	039386-2267	3394

22428 7590 08/20/2008
FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

MAIL DATE	DELIVERY MODE
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08/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,578	Applicant(s) CHAWLA ET AL.	
	Examiner Michael Pak	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 96-113 is/are pending in the application.
- 4a) Of the above claim(s) 103-113 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 96-102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7-24-06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 96-102 in the reply filed on May 7, 2008 is acknowledged. The traversal is on the ground(s) that the search and examination of group I and IV would not be burdensome to the examiner. This is not found persuasive because group I and IV would require a search in different database of protein and DNA respectively. Furthermore, Group I and IV are classified in separate classification.

The requirement is still deemed proper and is therefore made FINAL.

2. Amendment filed May 11, 2005 has been entered. Claims 96-102 are examined below. Claims 1-95 have been cancelled. Claims 103-113 are withdrawn.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 96-102 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The claims are directed to a carbohydrate associated protein of SEQ ID NO:5 which is an orphan protein whose function is not known. The specification on page 13 disclose the asserted utility of using the protein for links to diseases. However, there is no nexus between the claimed protein and the therapeutics for humans. The

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specification as filed does not disclose or provide evidence that points to a property of the claimed protein such that another non-asserted utility would be well established.

The claimed protein is an orphan protein whose function is not known thus has no known utility. The polypeptide lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. Thus, the asserted utility lacks substantial and specific utility because further research to identify or reasonably confirm a "real world" context of use is required. *Brenner V. Manson* 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966) stated that "Congress intended that no patents be granted on an chemical compound whose sole "utility" consists of its potential role as an object of use-testing ... a patent is not a hunting license." *Brenner* further states that "It is not a reward for the search, but compensation for its successful conclusion." Any utility of the nucleic acid encoding the protein or other specific asserted utility is directly dependent on the function of the protein. Any utility of the antibody or other specific asserted utility is directly dependent on the function of the protein also. A circular assertion of utility is created where the utility of the protein is needed to break out the circular assertion of utility. The polypeptides do not substantial utility because the skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its functional nexus with human therapeutics. Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used. The disclosed use for the nucleic acid molecule of the claimed invention is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence claimed. The claims directed to vectors and host

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cells do not have utility because the nucleic acid without utility is needed to practice the inventions.

Claims 96-102 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 96-102 are rejected under 35 U.S.C. 102(e) as being anticipated by Horne et al. (US 6,974,667).

Horne et al. disclose a polypeptide encoded by polynucleotide which has regions of 100% sequence identity and has biological activity of comprising an amino acid (see sequence comparison below).

Sequence comparison

Patent No. 6974667

APPLICANT: Horne, Darci T.

Query Match 70.7%; Score 1002; DB 4; Length 1551;

Best Local Similarity 87.6%; Pred. No. 1.9e-279;

Matches 1179; Conservative 0; Mismatches 0; Indels 167; Gaps 1;

Qy 72 TATTTCTCCCGCCTCCAAAGCAAACGACGTTCTGGTGAGGTGGAAGCGTGC GGGCTCCT 131

|||||

Db 144 TATTTCTCCCGCCTCCAAAGCAAACGACGTTCTGGTGAGGTGGAAGCGTGC GGGCTCCT 203

Qy 132 ATCTTCTGGAAGAACTCTTCGAGGGAAACTTGGAAAAAGAATGTTATGAAGAAATCTGTG 191

|||||

Db 204 ATCTTCTGGAAGAACTCTTCGAGGGAAACTTGGAAAAAGAATGTTATGAAGAAATCTGTG 263

Qy 192 TCTATGAAGAAGCAAGAGAAGTGTTTGAAAATGAAGTAGTCACTGATGAATTCTGGAGAC 251

|||||

Db 264 TCTATGAAGAAGCAAGAGAAGTGTTTGAAAATGAAGTAGTCACTGATGAATTCTGGAGAC 323

Qy 252 GATATAAGGGTAAGTGGTTTCCTTCGTCTCCTCAGAAGTATTAATTCCTCGGGATGAGGT 311

|||||

Db 324 GATATAAG----- 331

Qy 312 GCGTGGGTGGGCTTAGGACGCTTCACGACCCAGCTCAGCGGATGCCAAGCCTCTGGCTC 371

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Db 332 ----- 331

Qy 372 CAGGACCCACGGTGTCTCTCCAGGGAAGGGCAGCTCCGACTCTCCCCAAGGACCAGGCGG 431
|||||

Db 332 -----GGCGG 336

Qy 432 CTCCCCGTGCATCTCCAGCCCTGCCTCCACAACGGCTCTTGCCAGGACAGCATCTGGGG 491
|||||

Db 337 CTCCCCGTGCATCTCCAGCCCTGCCTCCACAACGGCTCTTGCCAGGACAGCATCTGGGG 396

Qy 492 CTACACCTGCACCTGCTCCCCGGCTATGAGGGCAGCAACTGCGAGCTGGCTAAAAATGA 551
|||||

Db 397 CTACACCTGCACCTGCTCCCCGGCTATGAGGGCAGCAACTGCGAGCTGGCTAAAAATGA 456

Qy 552 ATGTCACCCAGAGCGGACTGATGGGTGTCAACACTTCTGCCTCCCAGGACAGGAATCCTA 611
|||||

Db 457 ATGTCACCCAGAGCGGACTGATGGGTGTCAACACTTCTGCCTCCCAGGACAGGAATCCTA 516

Qy 612 CACGTGCAGCTGTGCTCAGGGCTACAGGCTTGGTGAGGACCACAAACAGTGTGTGCCCCA 671
|||||

Db 517 CACGTGCAGCTGTGCTCAGGGCTACAGGCTTGGTGAGGACCACAAACAGTGTGTGCCCCA 576

Qy 672 CGACCAGTGTGCCTGCGGGGTGCTGACCTCTGAGAAGCGTGACCGGATCTACAGGACCT 731
|||||

Db 577 CGACCAGTGTGCCTGCGGGGTGCTGACCTCTGAGAAGCGTGACCGGATCTACAGGACCT 636

Qy 732 CCCGTGGCAGGTAAAGTTAACAAATTCCGAAGGAAAAGACTTCTGTGGTGGTGTATAAT 791
|||||

Db 637 CCCGTGGCAGGTAAAGTTAACAAATTCCGAAGGAAAAGACTTCTGTGGTGGTGTATAAT 696

Qy 792 ACGGGAATTTTGTACTGACAACAGCAAAATGTTCACTGTTACACAGGAATATTACTGT 851
|||||

Db 697 ACGGGAATTTTGTACTGACAACAGCAAAATGTTCACTGTTACACAGGAATATTACTGT 756

Qy 852 AAAACATATTTTAAACAGAACGAGCCAAGACCCGCTGATGATCAAGATAACGCACGTCCA 911
|||||

Db 757 AAAACATATTTTAAACAGAACGAGCCAAGACCCGCTGATGATCAAGATAACGCACGTCCA 816

Qy 912 TGTGCACATGCGGTATGACGCGGACGCGGGGAGAATGACCTGTCACTGCTGGAGCTGGA 971

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Db      817 TGTGCACATGCGGTATGACGCGGACGCGGGGAGAATGACCTGTCACTGCTGGAGCTGGA 876

Qy      972 GTGGCCCATCCAGTGCCCAGGTGCGGGGCTCCCCGTGTGCACCCCTGAGAAAGACTTCGC 1031
|||||

Db      877 GTGGCCCATCCAGTGCCCAGGTGCGGGGCTCCCCGTGTGCACCCCTGAGAAAGACTTCGC 936

Qy      1032 TGAGCACCTCCTCATCCCACGCACCAGGGGCCTCCTCAGCGGCTGGGCACGCAATGGCAC 1091
|||||

Db      937 TGAGCACCTCCTCATCCCACGCACCAGGGGCCTCCTCAGCGGCTGGGCACGCAATGGCAC 996

Qy      1092 TGACCTGGGCAACTCGCTGACCACGCGGCCTGTCACTTGTGGAGGGGAGGAGTGCGG 1151
|||||

Db      997 TGACCTGGGCAACTCGCTGACCACGCGGCCTGTCACTTGTGGAGGGGAGGAGTGCGG 1056

Qy      1152 GCAGGTCCTGAATGTGACTGTCAACCACCAGGACCTACTGTGAGAGAAGCAGCGTGGCGGC 1211
|||||

Db      1057 GCAGGTCCTGAATGTGACTGTCAACCACCAGGACCTACTGTGAGAGAAGCAGCGTGGCGGC 1116

Qy      1212 CATGCACTGGATGGATGGAAGTGTGGTCACCAGAGAACACAGAGGCTCCTGGTTTCTCAC 1271
|||||

Db      1117 CATGCACTGGATGGATGGAAGTGTGGTCACCAGAGAACACAGAGGCTCCTGGTTTCTCAC 1176

Qy      1272 GGGGTCCTGGGCTCGCAGCCAGTAGGAGGGCAGGCTCACATGGTCCTTGTACCAAGGT 1331
|||||

Db      1177 GGGGTCCTGGGCTCGCAGCCAGTAGGAGGGCAGGCTCACATGGTCCTTGTACCAAGGT 1236

Qy      1332 CTCCAGGTACTCACTCTGGTTTAAACAGATCATGAACTAACTGAAACTCAGCTAGCCAGA 1391
|||||

Db      1237 CTCCAGGTACTCACTCTGGTTTAAACAGATCATGAACTAACTGAAACTCAGCTAGCCAGA 1296

Qy      1392 ATGAACAACACAACCGGAAGCGGGAT 1417
|||||

Db      1297 ATGAACAACACAACCGGAAGCGGGAT 1322
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5. Claims 96-102 are rejected under 35 U.S.C. 102(b) as being anticipated by Thoegersen et al. (US 5739281).

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Thoegersen et al. disclose a polypeptide which comprises the fragment of the claimed SEQ ID NO:5 because it has regions which are identical and has the biological activity of refolding or containing amino acids (see sequence comparison below).

Sequence comparison

Patent No. 5739281

APPLICANT: Thoegersen, Hans Christian

Query Match 37.9%; Score 196.5; DB 1; Length 487;

Best Local Similarity 52.3%; Pred. No. 2.1e-15;

Matches 45; Conservative 12; Mismatches 28; Indels 1; Gaps 1;

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Qy      1 MAGCVPLLQGLVLVLALHRVEPSVFLPASKANDVLRWKRAGSYLLEELFEGNLEKECYE 60
      ||| : |:      : | | ||||| :|: || | :|| |: |||: :|||:| | |
Db      1 MAGLLHLVLLSTALGGLLRPAGSVFLPRDQHRVLQRARRANSF-LEEVKQGNLERECLE 59

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Qy      61 EICVYEEAREVFEENEVVTDEFWRRYK 86
      | | ||||| |: ||||| :||
Db      60 EACSL EEAREVFEDAEQTDEFWSKYK 85

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6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael Pak/
Primary Examiner, Art Unit 1646
August 15, 2008